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10/783,958

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Robert S. Whitehouse

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EXAMINER

HAIDER, SAIRA BANO

ART UNIT

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/783,958	Applicant(s) WHITEHOUSE, ROBERT S.	
	Examiner SAIRA HAIDER	Art Unit 1796	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10/31/2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 81-112 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 81-112 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/31/2008 has been entered.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 81, 82, 84-111 and 113-122 are rejected under 35 U.S.C. 103(a) as being unpatentable over Noda (US 6,174,990) in view of Saito et. al. (Polymer International).

4. Noda discloses PHA (polyhydroxyalkanoates) are suitable for use as adhesives, in particular Noda recognizes copolymers comprising the claimed 3HB (3-hydroxybutyrate) and 4HB (4-hydroxybutyrate). Noda explicitly discloses using PHA adhesive to join two surfaces. The PHA is applied and then solidifies in order to secure the joint between the surfaces (abstract; col. 6, lines 32-34 and lines 38-40; col. 23, line 53 to col. 25, line 13).

5. However, Noda fails to disclose that the that the poly(3-hydroxybutyrate-co-4-hydroxybutyrate) has a glass transition temperature within the claimed range. Thus attention is directed towards the Saito reference which discloses the synthesis of poly(3-hydroxybutyrate-co-4-

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hydroxybutyrate) (3HB-co-4HB) and measures various properties of the resulting copolymers (abstract). Specifically, when 4HB is present in a mol% of 16, the 3HB-co-4HB has a glass transition temperature of -7°C (Table 5). Saito recognizes these copolymers as displaying various properties, including biodegradability (¶ joining pages 172-173).

6. Accordingly, it would have been obvious to one of ordinary skill in the art at the time of the invention to utilize the PHA of Saito, the 3HB-co-4HB, in the invention of Noda given that Saito recognizes that PHA as having improved elongation to break and is biodegradable (Table 5). In such substitution, the remaining disclosure of Noda is not modified and only the PHA of Saito is employed, wherein paragraphs 7 to 12 below describe the disclosure of Noda.

7. In reference to claims 111 and 113, drawn to the process of coating the adhesive on the substrate, Noda discloses that the PHA adhesive is applied as a liquid. Noda notes that the adhesives may be applied as solutions, in water or an organic solvent. Wherein the solvent must be removed after application for the adhesive to attain the required solid form; often heating is required to expedite the drying process (thus evaporating the solvent). (col. 23, line 54 to col. 24, lines 5).

8. In reference to claims 88-93, 95, and 97, which are drawn to the amounts of solvent included in the adhesive, Noda states that suitable solid contents of the solutions include from 5% to 95% (col. 24, line 28-30). Accordingly, the suitable solvent content can be calculated to be from 95% to 5%.

9. In reference to claim 96, Noda discloses that the adhesive is formed by dissolving PHA in a suitable solvent (col. 23, lines 63-67). Wherein Noda exemplifies that suitable solvents for dissolving PHAs include chloroform (col. 9, lines 24-26).

10. In reference to the claims 99-102 and 104 additives, Noda discloses formation of a PHA wherein an initiator is included in 6% by weight (Example 1).

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11. In reference to claim 114, Noda notes that the heating is conducted by passing the adhesive through the glass transition temperature of one of the components (col. 24, lines 22-26), given that the PHA of Saito has a Tg of -7°C (as noted above), the temperature required for cooling is within the claimed range of at most 40°C.

12. In reference to claims 119-122, regarding pressing a PHA between two surfaces to form the pressed PHA, it is noted that Noda discloses formation of molded articles using PHA. Specifically, Noda discloses blow molding an article by extruding the PHA composition into a closed hollow mold, expanding the mold, cooling to harden the plastic and then opening the mold to remove the article (col. 20, lines 31-37). Suitable pressures to expand the mold include 25-100 psi (col. 20, lines 38-41). Wherein the PHA copolymer of Saito (the 3HB-co-4HB) has a melting temperature of 130°C (Table 5). So during the blow molding process a temperature of at least 130°C is required, thus meeting the claimed limitation of a temperature of at most 150°C.

13. In reference to claims 85, 118, and 119 which claim a glass transition temperature of about -10°C, it is noted that the term "about" permits some tolerance and Saito reference discloses that the PHA copolymer has a Tg of -7°C. Wherein it is the examiner's position that one skilled in the art would have expected the composition of the Saito reference to have the same properties as the claimed composition. Additionally, a difference of 1-3°C in the glass transition temperature is not expected to change the properties of the composition. It has been held that a *prima facie* case of obviousness exists where the claimed ranges and prior art ranges do not overlap but are close enough that one skilled in the art would have expected them to have the same properties. *Titanium Metals Corp. of America v. Banner*, 778 F.2d 775, 227 USPQ 773 (Fed. Cir. 1985).

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14. In reference to claims 86 and 87, which are drawn to the inclusion of two different types of PHAs in the adhesive composition, it would have been obvious to one of ordinary skill in the art at the time of the invention to utilize a mixture of both the PHA disclosed by Saito and the PHA disclosed by Noda in order to obtain an adhesive mixture comprising properties of both components, including, improved elongation to break, as per the PHA of Saito, and increased biodegradability and/or compostability, as per the PHAs of Noda (Noda at col. 4, lines 20-24). Additionally, it is well settled that it is prima facie obvious to combine two ingredients, each of which is targeted by the prior art to be useful for the same purpose. *In re Linder* 457 F, 2d 506,509, 173 USPQ 356, 359 (CCPA 1972).

15. In reference to claim 94, which discloses that the solvent content is at most about 1% by weight, it is noted that the solvent content is recognized as a result effective variable because changing them will clearly affect the type of product obtained. See MPEP § 2144.05 (B). Case law holds that “discovery of an optimum value of a result effective variable in a known process is ordinarily within the skill of the art.” See *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980). In view of this, it would have been obvious to one of ordinary skill in the art to utilize a less than 5% solvent in the adhesive, in particular less than 1% so as to produce desired end results. Wherein utilization of less solvent results in a decreased heating time to remove the solvent and an increase in the thickness of the adhesive layer since more solids are present.

16. In reference to claims 98, which is drawn to the inclusion of two or more solvents, it is well settled that it is prima facie obvious to combine two ingredients, each of which is targeted by the prior art to be useful for the same purpose. *In re Linder* 457 F, 2d 506,509, 173 USPQ 356, 359 (CCPA 1972). Accordingly, it would have been obvious to one of ordinary skill in the art at the time

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of the invention to include two solvents in the adhesive taught by the combination of Saito and Noda.

17. In reference to claim 103, which discloses that the additive content is at most about 1% by weight, it is noted that the solvent content is recognized as a result effective variable because changing them will clearly affect the type of product obtained. See MPEP § 2144.05 (B). Case law holds that “discovery of an optimum value of a result effective variable in a known process is ordinarily within the skill of the art.” See *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980). In view of this, it would have been obvious to one of ordinary skill in the art to utilize a less than 6% additive in the adhesive, in particular less than 1% so as to produce desired end results. Wherein utilization of less additive (in this case initiator) results in a decrease in the polymerization time, which may be desired in situations requiring a greater amount of time for application of the adhesive.

18. In reference to claims 105-110 regarding the open time and surface tack time of the adhesive composition, it is noted that since the combination of prior art references teach the identical chemical structures, the properties applicant discloses and/or claims are necessarily present. “Products of identical chemical composition can not have mutually exclusive properties.” A chemical composition and its properties are inseparable. Therefore, since the prior art teaches the identical chemical structures, the properties applicant discloses and/or claims are necessarily present. *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). The burden shifts to the applicant to show an unobvious difference.

19. In reference to claims 115-117, which claims that different substrate surfaces are coated with the adhesive composition, it is noted that the claims merely modify or change the order of process steps. Noda exemplifies applying the adhesive between the two substrates (Example 19), wherein

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selection of any order of performing process steps is prima facie obvious in the absence of new or unexpected results. See MPEP § 2144.04. Since applicant has failed to show unexpected results for the claimed order of applying the adhesive, it is held that the selection of any order, including the claimed order, is prima facie obvious.

20. Claims 83 and 112 are rejected under 35 U.S.C. 103(a) as being unpatentable over Noda (US 6,174,990) in view of Saito et. al. (Polymer International), as applied above, and in further view of Marecki (US 4,655,768).

21. Saito and Noda apply as discussed above, Noda discloses that the PHA can be utilized as a pressure-sensitive adhesive in bandages (col. 24, lines 62-63). However, the reference fails to disclose the adhesive layer thickness. Thus attention is directed towards the Marecki reference which discloses bandages having a pressure-sensitive adhesive layer wherein suitable thicknesses include 10 to 150 microns. Marecki notes that the thickness of the adhesive layer has an effect on controlling the rate of dissolution of the drug (col. 3, lines 2-6 and 59-61). Accordingly, it would have been obvious to one of ordinary skill in the art at the time of the invention to utilize the PHA adhesives taught by Saito and Noda in bandages, wherein the thickness of the adhesive layer is within 10 to 150 microns. The motivation is provided by the fact that Noda recognizes the PHAs as suitable for use in bandages and Marecki guides one skilled in the art as to suitable adhesive layer thicknesses.

Double Patenting

22. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application

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claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

23. Claims 81-112 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 12, 16, 19-22, 25-28 and 67 of copending Application No. 10/783,995 (US 2004/0220355 A1). Although the conflicting claims are not identical, they are not patentably distinct from each other because the '995 application claims a blend comprising at least a copolymerized PHA, wherein suitable comonomers include 3-hydroxybutyrate and 4-hydroxybutyrate. The '995 application fails to claim that the blend is capable of functioning as an adhesive coating on a substrate to form an article, as claimed herein, however, the enabling disclosure makes known this limitation [0098], and discloses a thickness of at most about 300 microns [0164]. Further, the '995 application fails to claim the glass transition temperature, however, Examples 10-11 (in Table 3), makes known this limitation. In reference to the herein claimed properties (open time and surface tack time), the enabling disclosure of the '995 application discloses that suitable PHA compositions with the claimed molecular weight, glass transition temperature, crystallinity, and polydispersity as claimed by applicant, thus, it is the examiner's position that the polymers and compositions would inherently possess the claimed surface tack time, peel bond strength, and open time (claim 36, [0120-0125]). Thus, it would have been obvious to one of ordinary skill in the art at the time of the invention to form the herein claimed composition.

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24. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

25. Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SAIRA HAIDER whose telephone number is (571)272-3553. The examiner can normally be reached on Monday-Friday from 10am-6pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Randy P. Gulakowski can be reached on (571) 272-1302. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Randy Gulakowski/
Supervisory Patent Examiner, Art Unit 1796

Saira Haider
Examiner
Art Unit 1796

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